K120799

5.0 510(k) Summary

MAR 30 2012

5.1. Submitter

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Date Prepared	01 November 2011

5.2. Device Identification

Trade Name	Arisure™ Neutral Valve
Common Name	Needle-free access device, needle-free connector, luer access device
Classification	Intravascular Administration Set Product Code – FPA Regulation 21 CFR 880.5440

5.3. Predicate Devices

Device	Manufacturer	510(k)
B3300 MicroCLAVE® Connector; C1000 CLAVE® Connector	ICU Medical, Inc.	K970855

5.4. Device Description

The Arisure™ Neutral Valve is a sterile, single-use, swab-able, normally closed, luer-activated, valved connector. The Arisure™ Neutral Valve consists of five primary components: lower housing, upper housing, retention ring, pre-slit silicone piston, and lubricating silicone oil. The lower housing, made of polycarbonate, consists of a male luer and a long feature that provides support for the silicone piston to move upon. The pre-slit silicone piston attaches to the lower housing. A series of round protrusions on the inside of the silicone piston provides sliding seals over the long feature on the lower housing. These sliding seals allow fluid to travel through the silicone piston when the piston is accessed with a male luer. The retention ring, made of polycarbonate, fits over the silicone piston and provides extra rigidity. The silicone piston and top housing together comprise the female end of the needle-free valve. The top housing, made of polycarbonate, fits over the top of the piston and is permanently affixed to the bottom housing. When pressed downward by a male luer, the slit in the piston opens, and the sliding seal on the inside of the piston opens a fluid pathway through the device. Silicone oil is used to lubricate the silicone piston. The Arisure™ Neutral Valve does not contain any natural rubber latex.

5.5. Intended Use

The Arisure™ Neutral Valve is a single use, sterile, non-pyrogenic device intended for use as an accessory to intravascular administration sets for the administration or withdrawal of fluids from a patient through a cannula placed in the vein or artery. The Arisure™ Neutral Valve may be used with low-pressure power injectors up to 300 psi.

The indications statement for the Arisure™ Neutral Valve differs from the indications statement of the predicate device (presented in 510(k) K970855) in that it additionally states that the Arisure™ Neutral Valve can be used to withdraw fluid from a patient, rather than just administer fluid. This difference is not critical to the intended therapeutic use of the device, and the difference does not affect the safety and effectiveness of the device when used as indicated.

The primary concern with the withdrawal of fluids from a patient through an cannula placed in the vein or artery of a patient is damage that can occur to the withdrawn fluid sample; damage to blood. In addition to the traditional tests for material hemocompatibility presented in the biocompatibility section (section 15), additional testing was also conducted on the Arisure™ Neutral Valve to determine whether the withdrawal of blood using the Arisure™ Neutral Valve caused damage to the blood. Section 15 details this test, which shows that when compared to blood withdrawn using a 21GA needle, the Arisure™ Neutral Valve has less hemolysis. A general threshold for assessing the hemolytic property of a given material is that hemolytic percentages below 2% are considered non-hemolytic (ASTM F 756-00). Both the 21GA needle and the Arisure™ Neutral Valve had hemolytic percentages below 2%.

In addition to the hemolytic testing conducted on the Arisure™ Neutral Valve, the predicate CLAVE® device is also used for the withdrawal of fluid. ICU Medical Instructions M1-1053 Rev01 illustrates the use of the CLAVE® device for withdrawing blood from a patient.

5.6. Predicate Device Comparison (Technological Characteristics)

A direct comparison of the technical and performance characteristics of the Arisure™ Neutral Valve and the technical and performance characteristics of the predicate device demonstrates equivalency. Minor differences in subject and predicate device characteristics do not introduce any new safety or efficacy concerns.

Table 5.6: Device Technological Comparison

	Subject Device Arisure™ Neutral Valve	**Predicate Device MicroCLAVE® B3300 Connector and CLAVE® C1000 Connector (510(k):K970855)**
Materials	**Neutral Valve Materials:**	**Materials per 510(k): K970855**
	Lower Housing (Internal Conduit) - Polycarbonate	Internal Conduit- Polycarbonate
	Pre-slit Silicone Piston: silicone rubber	Silicone Seal[Silicone Piston] - Silicone Rubber
	Lubricant - Fluorosilicone	Lubricant - Fluorosilicone
	Upper Housing - Polycarbonate	[upper]Housing - Polyester
	Retention Ring- Polycarbonate	
Principles of Operation	The female Luer valve opens to permit the introduction or withdrawal of fluids when accessed by a male Luer tip. This access deforms a compressible element that returns to its original shape through the mechanical properties of the deformable element.	The female Luer valve opens to permit the introduction or withdrawal of fluids when accessed by a male Luer tip. This access deforms a compressible element that returns to its original shape through the mechanical properties of the deformable element.
Technology and Design	When activated by a male Luer, a pre-slit elastomeric sleeve advances over an internal post, opening a fluid pathway that connects the female and male ends of the device.	When activated by a male Luer, a pre-slit elastomeric sleeve advances over an internal post, opening a fluid pathway that connects the female and male ends of the device.

5.7. Discussion of Non-clinical tests

The following non-clinical tests have been done in support of the substantial equivalence of the Arisure™ Neutral Valve to the Predicate CLAVE® devices:

- Microbial Ingress Testing
- Biocompatibility Testing
- Liquid Leak (open position)
- Liquid Leak (closed position)
- Vacuum Leak (open position)
- Vacuum Leak (closed position)
- Flow Rate
- Tensile Strength
- Disconnection Bolus

Results from non-clinical testing indicate that the Arisure™ Neutral valve is as safe and effective as the predicate device. Testing conducted that reference the design verification and validation testing of the Arisure™ Neutral valve meet pre-determined acceptance criteria for the device. Testing conducted as a direct comparison of the Arisure™ Neutral valve and predicate device demonstrate that the equivalence of the devices.

5.8. Conclusion

The Arisure™ Neutral Valve is equivalent to the predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Yukon Medical, LLC
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25TH Street N.W.
Buffalo, Minnesota 55313

MAR 3 0 2012

Re: K120799
Trade/Device Name: Arisure™ Neutral Valve
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 15, 2012
Received: March 16, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): K120799

Device Name: Arisure™ Neutral Valve

Indications for Use:

The Arisure™ Neutral Valve is a single use, sterile, non-pyrogenic device intended for use as an accessory to intravascular administration sets for the administration or withdrawal of fluids from a patient through a cannula placed in the vein or artery. The Arisure™ Neutral Valve may be used with low-pressure power injectors up to 300 psi.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 3/29/2012
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120799